IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

Canopy Growth Corporation, Plaintiff, v. GW Pharma Limited and GW Research Limited, Defendants.	)	Civil Action No. 6:20-cv-01180-ADA **JURY TRIAL DEMANDED**

PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff Canopy Growth Corporation ("Canopy") files this first amended complaint for patent infringement against Defendants GW Pharma Limited and GW Research Limited (collectively, "Defendants") and in support thereof alleges and avers as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, specifically including 35 U.S.C. § 271.

THE PARTIES

2. Canopy is a publicly traded corporation, incorporated in Canada, with its head office located at 1 Hershey Drive, Smiths Falls, Ontario, Canada, K7A 0A8.

3. On information and belief, GW Pharma Limited is a private limited company organized under the laws of the United Kingdom, with a principal place of business at Sovereign House, Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ United Kingdom. On information and belief, GW Pharma Limited is a wholly owned subsidiary of GW Pharmaceuticals Limited (formerly GW Pharmaceuticals PLC).

4. On information and belief, GW Research Limited is a private limited company organized under the laws of the United Kingdom, with a principal place of business at Sovereign House, Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ United Kingdom. On information and belief, GW Research Limited is a wholly owned subsidiary of GW Pharmaceuticals Limited.

JURISDICTION AND VENUE

5. Canopy asserts claims for patent infringement against Defendants arising under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c). Defendants are foreign entities and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

7. This Court has personal jurisdiction over Defendants consistent with the requirements of the Due Process Clause of the United States Constitution and the Texas Long Arm Statute, due at least to their substantial business in Texas and this judicial district, including: (1) regularly doing or soliciting business, engaging in other persistent conduct, and/or deriving substantial revenue from goods sold and/or services provided to Texas residents; and (2) at least part of the infringing activities alleged herein.

8. On information and belief, Defendants are wholly owned subsidiaries of GW Pharmaceuticals Limited (formerly GW Pharmaceuticals PLC), and GW Pharmaceuticals Limited has 100% direct ownership of Defendants. *See* Ex. G at 84. On information and belief, Defendants manufacture Epidiolex, a pharmaceutical formulation of cannabidiol ("CBD"), and import, have imported, sell, and/or offer to sell Epidiolex in this district and across the state of

Texas. *See, e.g.*, Ex. G at 1 (GW Pharmaceuticals PLC "Annual Report and Accounts" for 2019 stating that "[w]e launched Epidiolex on 1 November 2018 in the US market after FDA approval"), 5 (stating that one of GW Pharmaceuticals PLC's business strategies is to "[c]ommercialise our lead product candidate Epidiolex in Dravet syndrome and LGS in the US and Europe using our own commercial organization"). On information and belief, Defendants' parent company, GW Pharmaceuticals Limited, retains global commercial rights for Epidiolex. *See id.* at 1. On information and belief, Defendants rely on funding from their parent company, GW Pharmaceuticals Limited. *See, e.g.*, Ex. I, 3; Ex. J, 4.

9. On information and belief, Defendants' parent company, GW Pharmaceuticals Limited, treats employees and sales of its subsidiaries, including Defendants, as its own and reports on "its" activities in the United States. Ex. G, 7 (GW Pharmaceuticals PLC "Annual Report and Accounts" for 2019 stating that GW Pharmaceuticals PLC's "product net sales include sales of Epidiolex, which we launched in the United States in November 2018"), 51 (describing "GW Pharmaceuticals plc (the 'Company') and its subsidiaries (the 'Group')"), 5 (describing "the Group's global R&D programs"), 7 (stating that "[t]he Group considers that the primary key performance indicator is progress on sales of Epidiolex in the United States"), 7, (stating that "we recorded revenues of $311.3 million" in the year ended 31 December 2019 and describing Epidiolex as "the Group's first own commercial product, and first marketed in the United States"); 8 (describing "Total Group Employees" including "all of the Group's global employees, and Executive Directors").

10. On information and belief, Epidiolex, which is produced using Canopy's patented extraction process, has been prescribed to patients in this district and across the state of Texas. *See, e.g.*, *id.* at 1 (stating that GW Pharmaceuticals PLC "launched Epidiolex on 1

November 2018 in the US market after FDA approval"); Ex. H at 2 (describing that Epidiolex will be marketed in the United States by a "U.S. subsidiary of GW Pharmaceuticals plc"). Additionally, on information and belief, Defendants enlisted residents of Austin, TX, which is within this district, to participate in a study conducted as part of obtaining Food and Drug Administration (FDA) approval of Epidiolex. *See* Exhibit F; *see also* Ex. H at 1 (describing FDA approval of Epidiolex as "the culmination of [GW Pharmaceuticals PLC's] many years of partnership with patients, their families, and physicians in the epilepsy community"), Ex. G at 1 (GW Pharmaceuticals PLC "Annual Report and Accounts" for 2019 stating that "[w]e have begun recruiting patients for a pivotal trial of Epidiolex").

11. This Court has personal jurisdiction over Defendants, directly or through intermediaries, including Defendants' U.S.-based sales team, because Defendants have committed acts within Texas giving rise to this action and/or have established minimum contacts with Texas such that personal jurisdiction over Defendants would not offend traditional notions of fair play and substantial justice. On information and belief, Defendants, without authority, import Epidiolex, which is made by Canopy's patented extraction process, into the United States (including the state of Texas and within this district) and/or have Epidiolex imported into the United States (including the state of Texas and within this district). On information and belief, Defendants also offer to sell, sell, and/or use Epidiolex within the United States (including the state of Texas and within this district). On information and belief, Defendants also actively induced and continue to induce affiliated companies (e.g., Greenwich Biosciences Inc.), third parties (e.g., physicians and/or pharmacies), and end users (e.g., patients) to import, have imported, sell, offer to sell, and/or use Epidiolex in the United States (including the state of Texas and within this district).

12. On information and belief, Defendant GW Pharma Limited's "core expertise" is "the extraction, purification and formulation of cannabinoid dosage forms" and its "role within the GW Pharmaceuticals Group ('the Group') is to provide manufacturing and research and development services to fellow subsidiaries and commercial partners." Ex. I at 2. On information and belief, Defendant GW Research Limited's "primary purpose is to produce and distribute the Group's products to third-party customers and other GW Pharmaceuticals Group companies." Ex. J at 5. On information and belief, Defendant GW Pharma Limited, acting in concert with at least the other named Defendants, "carries out shipments of Epidiolex to its US-based fellow subsidiary," which resulted "in the recognition of £150.7 million of revenue during the current period (15-month period ended 31 December 2018: £44.1 million)." Ex. I at 2. On information and belief, Epidiolex is marketed throughout the United States, including in the state of Texas, through a commercial organization consisting of sales, medical affairs, marketing, and market access/payer teams.

13. On information and belief, Defendants have placed and continue to place products produced using Canopy's patented process, including at least Epidiolex, into the stream of commerce via an established distribution channel with the knowledge and/or intent that Epidiolex was imported into, sold, offered for sale, and used in the United States, including in the state of Texas and this district, and continues to be imported into, sold, offered for sale, and used in the United States, including in the state of Texas and this district.

14. Accordingly, this Court may properly exercise personal jurisdiction over Defendants.

THE PATENT-IN-SUIT

15. U.S. Patent No. 10,870,632 (the "'632 Patent"), titled "Process For Producing An Extract Containing Tetrahydrocannabinol And Cannabidiol From Cannabis Plant Material, And Cannabis Extracts," was duly and legally issued by the United States Patent and Trademark Office (USPTO) on December 22, 2020. Canopy is the owner by assignment of the entire right, title, and interest in and to the '632 Patent, including the sole and undivided right to sue for infringement. A true and correct copy of the '632 Patent is attached hereto as Exhibit A.

BACKGROUND OF THE DISPUTE

16. This dispute relates to Defendants' continued, unauthorized use of Canopy's patented processes for extracting cannabidiol from cannabis plant material. Cannabidiol, or CBD, is one ingredient found in plants of the cannabis family that includes what are commonly known as hemp and marijuana. Unlike Δ^9-tetrahydrocannabinol, or THC—another of the active ingredients in cannabis—CBD does not cause noticeable intoxicating, euphoric effects. Current research is ongoing, but indicates that CBD offers significant therapeutic benefits, including anti-inflammatory, analgesic, antiemetic, and anti-seizure effects.

17. Canopy is a Canadian corporation that focuses on legal development of hemp and marijuana-based compounds and resulting products, with operations in countries across the world. Canopy produces, distributes, and sells a diverse range of cannabis and hemp-based products and other consumer products for both recreational and medical purposes under a portfolio of distinct brands in Canada pursuant to the *Cannabis Act*, and globally pursuant to applicable international and Canadian legislation, regulations, and permits. Subsequent to the passage of the U.S. Agricultural Improvement Act of 2018 in December 2018, Canopy began building its hemp supply chain in the United States through its investment in hemp growing capability and in

processing, extraction and finished goods manufacturing facilities. Canopy sells a line of hemp-derived CBD isolate products under the First & Free Brand, including oils, softgels and topical creams, and in September 2020, Canopy launched Martha Stewart CBD, a new line of premium quality, hemp-derived wellness gummies, oils and softgels.

18. Canopy acquired all right, title, and interest in the '632 Patent in connection with its acquisition of Germany's C3 Cannabinoid Compound Company, founded by top global herbal medicine manufacturer Bionorica SE. The '632 Patent is part of a patent family dating back more than twenty years to October 17, 2000, with the filing by named inventor Adam Mueller of German Patent Application No. 100 51 427, to which the '632 Patent claims priority. The '632 Patent family relates to pioneering processes for producing an extract from cannabis plant matter containing CBD using carbon dioxide (CO_2). *See* Ex. A at Abstract. The potential therapeutic applications of CBD and other cannabis active principles were a motivating factor in developing the processes described and claimed in the '632 Patent. Indeed, the '632 Patent identifies a variety of anticipated medical applications, notably including the use of CBD as an anti-epileptic. *See, e.g.*, *id.* at 3:53-4:3.

19. On information and belief, Defendants are part of an affiliated group of biopharmaceutical companies involved in the development and commercialization of cannabinoid therapeutics. On information and belief, Defendants' leading cannabinoid product is Epidiolex, an anti-epileptic medication consisting of a pharmaceutical formulation of highly purified CBD. As detailed below, on information and belief, Defendants manufacture the active pharmaceutical ingredient in Epidiolex—CBD—using the CO_2-based extraction process described and claimed in the '632 Patent. On information and belief, Epidiolex was approved by the FDA on June 25, 2018 for the treatment of seizures associated with certain diseases. On information and belief, Epidiolex

became commercially available in the United States on November 1, 2018. On information and belief, Defendants set a list price for Epidiolex of $1,235 per 100mL bottle, with a weighted average gross price of approximately $32,500 per patient per annum. On information and belief, Defendants reported approximately $366 million in net product sales of Epidiolex in the United States in the first nine months of 2020. On information and belief, the success of Defendants' Epidiolex is based, at least in part, on Defendants' use, without authority, of the CO_2 extraction process described and claimed in the '632 Patent, which enables the production of a CBD-rich extract from cannabis material.

20. On information and belief, Defendants are aware, or should be aware, that the extraction process used to manufacture Epidiolex infringes the claims of the '632 Patent. Although the '632 Patent recently issued, on information and belief, Defendants have been monitoring the '632 Patent family for over fourteen years. In May 2006, for instance, GW Pharmaceuticals PLC (now GW Pharmaceuticals Limited), the parent company of Defendants, proactively challenged the issuance of a European counterpart application (European Patent No. EP 1 326 598) by filing an opposition before the European Patent Office. By the time GW Pharmaceuticals PLC filed its opposition, the parent application of the '632 Patent—U.S. Patent Application No. 10/399,362, which issued as U.S. Patent No. 8,895,078 (the "'078 Patent")—had already been filed. In light of GW Pharmaceuticals PLC's (now GW Pharmaceuticals Limited) monitoring and proactive steps to invalidate a European counterpart, Defendants knew, or should have known, of the existence of the U.S. counterpart applications in the '632 Patent family.

21. Notably, on information and belief, in 2016 Defendants' parent company GW Pharmaceuticals PLC (now GW Pharmaceuticals Limited) considered using Canopy's predecessor in interest, Bionorica—an early pioneer of CO_2 extraction techniques—as its

processor for extracting CBD. By this time, the '078 Patent had already issued and the application that ultimately issued as the '632 Patent had been filed. Although that deal did not materialize, these negotiations further evidence that Defendants have been aware of the patented processes described and claimed in the '078 and '632 Patents for many years. Indeed, in 2017, Defendants' parent company GW Pharmaceuticals PLC (now GW Pharmaceuticals Limited) declined a license to the '078 Patent. This case is not about restricting patient access to Epidiolex. Rather, Canopy brings this action to put a stop to Defendants' knowing and unauthorized use of Canopy's intellectual property.

PATENT INFRINGEMENT CLAIMS

Count I: Infringement of U.S. Patent No. 10,870,632

22. Canopy re-alleges and incorporates herein by reference the allegations contained in Paragraphs 1-21 above.

23. The '632 Patent generally relates to a process for producing an extract containing tetrahydrocannabinol (THC), CBD, and optionally the carboxylic acids thereof from cannabis plant material. *See* Ex. A at 1:23-26. The patent describes that one "object of the present invention [is] to provide Δ^9-tetrahydrocannabinol, Δ^8-tetrahydro-cannabinol and cannabidiol in pure form and as an extract in the form of preparations for medical applications," and to obtain these active principles from hemp varieties having low cannabinoid contents (e.g., fiber-type hemp) because of their better availability. *Id.* at 4:59-67. When hemp of the fiber-type is used as a starting material, cannabidiol (and/or the carboxylic acids thereof) are found as the main constituents in the primary extract. *Id.* at 6:45-48. The patent explains that "[a]s cannabidiol taken for itself has interesting pharmacological properties while further lacking the psychotropic

hallucinogenic effect of Δ^9-THC, cannabidiol itself is also of interest for practical application because it may be used, e.g., as an anti-epileptic." *Id.* at 9:29-33.

24. The processes described in the '632 Patent significantly improved upon other approaches to enriching, isolating, and/or synthesizing cannabinoids, and in particular those that relied on hexane and ethanol extracts. The extract produced from the patented processes can be used as an active principle for the production of a medication (e.g., for the indications described above, including as an anti-epileptic). *Id.* at 3:53-4:3, 14:22-27.

25. On information and belief, Defendants infringe one or more claims of the '632 Patent, either literally or under the doctrine of equivalents. Non-limiting examples of such infringement are provided below, based on the limited information currently available to Canopy.

Claim 1 of the '632 Patent recites as follows:

> A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a *cannabis* plant material or a primary extract thereof, said process comprising:
>
> (1) subjecting the *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and
>
> (2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO_2.

Claim 14 of the '632 Patent recites as follows:

> A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD) from a *cannabis* plant material or a primary extract thereof, said process comprising:
>
> (1) decarboxylating cannabinoid carboxylic acids in the *cannabis* plant material or primary extract thereof;
>
> (2) subjecting the decarboxylated *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and
>
> (3) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO_2.

26. On information and belief, Defendants perform each and every limitation of Claims 1 and 14, as well as many of the dependent claims of the '632 Patent. On information and belief, Defendants perform a process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD). *See generally* Ex. B ("Our Cannabidiol Manufacturing Process"). The extract is produced from a cannabis plant material or a primary extract thereof. For example:

Ex. B at 1.

- The finished product is lightly compressed into bales and labelled with an individual batch item code and batch number for traceability, and prepared for dispatch to the processing center.
- On arrival at the processing plant, the dried plant material is pelleted, allowing the batch to be stored in a stable form for an extended period prior to further processing.

Id. Additionally, on information and belief, Defendants use "plants of *Cannabis sativa* L, with defined chemical profiles and containing consistent levels of CBD as the major cannabinoid and a low level of delta-9-tetrahydrocannabinol (THC)." Ex. C at 12; *see also* Ex. D at 15:15-19 ("High CBD chemovars were grown, harvested and dried and stored in a dry room until required. The botanical raw material (BRM) was finely chopped using an Apex mill fitted with a 1 mm screen. The milled BRM was stored in a freezer for up to 3 months prior to extraction.").

27. On information and belief, Defendants' process includes decarboxylating cannabinoid carboxylic acids in the cannabis plant material or primary extract thereof. For example, Defendants achieve "active CBD via decarboxylation":

ACHIEVING ACTIVE CBD VIA DECARBOXYLATION

Since cannabinoids are naturally produced in the plant in their acid form, a chemical reaction called decarboxylation is used to convert the inactive acid into the active molecule CBD.

- Pelleted material is milled to create a uniform particle suitable for extraction.
- Naturally occurring cannabidiolic acid is heated to convert it to CBD that is biologically active.

Ex. B at 1. *See also* Ex. E at 5:33-40 ("In a first aspect the invention provides a method of extracting cannabinoids from plant material comprising a decarboxylation step[.]").

28. On information and belief, Defendants' process includes subjecting the decarboxylated cannabis plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components. For example, "[a]fter decarboxylation is complete, the raw material is loaded into an extraction column and CO_2 is passed through at a pre-specified temperature until the extraction process is complete":

YIELDING A CBD-RICH EXTRACT

After decarboxylation is complete, the raw material is loaded into an extraction column and CO_2 is passed through at a pre-specified temperature until the extraction process is complete.

CO_2 extraction process destroys any bacteria present in the plant material and yields a CBD-rich extract containing cannabinoids and other natural plant-based components, including waxes and terpenes (aromatic compounds).

Ex. B at 1. *See also* Ex. D at 15:29-30 ("Extraction No 1 was performed using liquid CO_2 at 60 bar/10° C. to produce botanical drug substance (BDS)."); Ex. E at 5:33-40 ("In a first aspect the invention provides a method of extracting cannabinoids from plant material comprising a decarboxylation step, an extraction with liquid carbon dioxide (CO_2), and a step to reduce the proportion of non-target materials in the extract, characterised in that the extraction with liquid CO_2 is conducted under sub-critical conditions at a temperature of between 5-15° C and a pressure of between 50-70 bar.").

29. On information and belief, Defendants' process includes reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO_2. For example:

> In a preferred embodiment liquid CO_2 is removed by depressurisation and the recovered extract held at a temperature in the range from -15°C to -20°C.

Id. at 7:21-23.

30. In view of the foregoing, Defendants infringe at least Claims 1 and 14 of the '632 Patent in violation of 35 U.S.C. § 271. Canopy's investigation of Defendants' operations and manufacturing process is ongoing. To the extent it is determined that Defendants use Canopy's patented processes to produce CBD (the active pharmaceutical ingredient in Epidiolex) in the United States, Defendants directly infringe the '632 Patent in violation of 35 U.S.C. § 271(a).

31. To the extent that Defendants, and/or third-party contractors under the direction of Defendants, use the patented processes to produce the CBD in Epidiolex outside the United States, Defendants infringe the '632 Patent in violation of 35 U.S.C. § 271(g). On information and belief, Defendants, without authority, import or have Epidiolex imported into the United States and/or offer to sell, sell, and/or use Epidiolex within the United States. On information and belief, the active pharmaceutical ingredient in Epidiolex is CBD extracted using the process(es) claimed in the '632 Patent, and the extracted CBD is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

32. Additionally, on information and belief, Defendants are liable for actively inducing infringement of the '632 Patent under 35 U.S.C. § 271(b) by having knowledge of the

’632 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, infringement of the ’632 Patent, with specific intent, by others. For example, on information and belief, Defendants, with knowledge that the active pharmaceutical ingredient in Epidiolex, CBD, is made outside the United States by a process patented by the ’632 Patent, have actively induced and continue to induce affiliated companies (e.g., U.S.-based subsidiary Greenwich Biosciences Inc.), third parties (e.g., physicians and/or pharmacies) and end users (e.g., patients) to import, have imported, sell, offer for sale, and/or use Epidiolex in the United States in violation of 35 U.S.C. § 271(g). For example, on information and belief Defendants produce and distribute products, including Epidiolex, to third-party customers and affiliated companies, including at least U.S.-based affiliate Greenwich Biosciences Inc., with the knowledge and intent that those products, including Epidiolex, will be sold, offered for sale, and/or used in the United States in violation of 35 U.S.C. § 271(g). On information and belief, Defendants, acting alone or in concert with affiliated companies and/or other intermediaries, market Epidiolex throughout the United States through a commercial organization consisting of sales, medical affairs, marketing, and market access/payer teams. On information and belief, Defendants’ marketing plan includes a combination of community neurology/epilepsy meetings, patient advocacy events, an extensive program for U.S. clinicians to share their Epidiolex experiences and a media-based awareness program.

33. On information and belief, Defendants’ infringement of the ’632 Patent has been and continues to be willful and deliberate. As detailed above, on information and belief, Defendants have had actual and constructive notice of the ’632 Patent family since at least as early as May 2006, and knowledge of the ’632 Patent as early as its U.S. filing date and no later than December 22, 2020, the date of filing of Canopy’s original Complaint. Despite having knowledge

of the ’632 Patent and its infringement, on information and belief, Defendants have and continue to: (1) use Canopy’s patented processes to extract CBD in the United States and/or outside the United States; (2) import and/or have Epidiolex imported into the United States, with knowledge that the active pharmaceutical ingredient of Epidiolex is CBD produced by Canopy’s patented processes; and/or (3) offer to sell, sell, and/or use Epidiolex within the United States in violation of one or more of 35 U.S.C. §§ 271(a) and (g). On information and belief, Defendants also have and continue to actively induce others to import, offer to sell, sell, and/or use Epidiolex, the active pharmaceutical ingredient of which is CBD produced by Canopy’s patented processes, within the United States in violation of 35 U.S.C. § 271(b).

34. As a direct and proximate result of Defendants’ acts of infringement, Canopy has suffered and continues to suffer damages and irreparable harm.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Canopy hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Canopy prays for judgment in its favor granting the following relief:

A. A finding that Defendants have infringed the ’632 Patent in violation of one of more subsections of 35 U.S.C. § 271, including but not limited to subsections (a), (b), and/or (g);

B. An award of damages pursuant to 35 U.S.C. § 284 adequate to compensate Canopy for Defendants’ infringement of the ’632 Patent, including both pre- and post-judgment interest and costs as fixed by the Court;

C. A finding that Defendants' infringement of the '632 Patent has been willful and an appropriate enhancement of damages pursuant to 35 U.S.C. § 284;

D. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and a corresponding award of Canopy's reasonable attorneys' fees incurred in connection with the litigation; and

E. Any additional and further relief the Court may deem just and proper under the circumstances.

July 7, 2021

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